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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

E. SELLERS et al.

Application No.: 10/715,548

Filed: November 19, 2003



Attorney Docket No. 62805.000040

Art Unit: Unassigned

Examiner: Unassigned

For: USE OF INHIBITORS OF CYP2A6 FOR REGULATING NICOTINE METABOLISM

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with 37 C.F.R. §§ 1.56, 1.97, and 1.98, Applicants respectfully request consideration of the reference listed on the attached Form PTO-1449. Since copies of the cited references were previously submitted in prior U.S. Patent Application No. 09/214,851 (Attorney Docket No. 62805.000005) by the Applicants and is a case to which the present case claims priority, copies of the cited references are not being submitted herewith. For the Examiner's convenience a copy of the signed PTO-1449 from the priority case is provided. Applicants will provide any reference listed at the request of the Examiner.

Additionally, Applicants bring to the Examiner's attention related case 09/584,669 (Attorney Docket No. 62805.000020). A copy of the references cited therein are also cited to the Examiner.

Applicants respectfully point out that the submission of the listed document in this Information Disclosure Statement is not an admission that it is a prior art or that it is material to

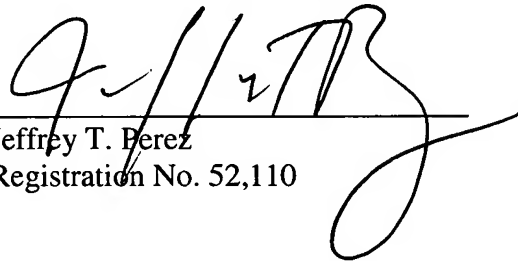
patentability of any claims of the application. Also, the submission of this Information Disclosure Statement is not an indication that a search has been made.

Applicants respectfully request that the Examiner consider the reference cited on the Form PTO-1449 and that the Examiner indicate that the reference has been considered in this application by returning a copy of the Form PTO-1449 with the Examiner's initials in the left column per MPEP 609.

This IDS is submitted prior to the issuance of a first Office Action on the merits; therefore, it is believed that no fees are required in connection therewith. If any fees are necessitated by the filing of this Information Disclosure Statement, please charge the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,
HUNTON & WILLIAMS LLP

By:

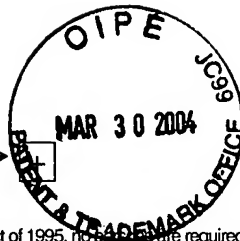

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Dated: March 30, 2004

JTP/sdw

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PTO/SB/08A (08-00)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

Complete if Known

Application Number	10/715,548
Filing Date	November 19, 2003
First Named Inventor	E. SELLER et al.
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	62805.000040

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	1.	5653987		Modi et al.	08-1997	
	2.	5760049		Viner	06-1998	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Date of Publication of Cited Document MM-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ₆
		Office ³	Number ⁴	Kind Code ⁵ (if known)			
	3.	WO	95/34679		12/1995		
	4.	SU	1803032 A1		03/1993		

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	5.	NAKAJIMA, M et al., Characterization of CYP2A6 involved in 3'-hydroxylation of cotinine in human liver microsomes, J. Pharmacol. Exp. Therap., (1996), Vol. 277, No. 2, pp. 1010-1015	
	6.	NAKAJIMA, M. et al., Role of human cytochrome P4502A6 in C-oxidation of nicotine, Drug Metabol. Disp. (1996), Vol. 24, No. 11, pp. 1212-1217	
	7.	TSUJIMOTO, A. et al., Potent inhibitory action of pilocarpine on hepatic drug metabolism, Jpn. J. Pharmacol., (1972) Vol. 22, No. 5, 736	

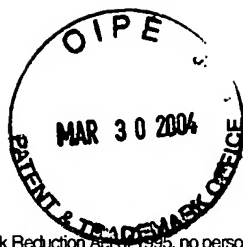
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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 2

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Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	62805.000040

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	8.	FOTH, H. et al., Nicotine metabolism in isolated perfused ling and liver of phenobarbital- and benzoflavone-treated rats, Arch. Toxicol., (1991) Vol. 65, No. 1, pp. 68-72	
	9.	KYEREMATEN, G. A. et al., Metabolism of nicotine by hepatocytes, Biochem. Pharmacol., (1990) Vol., No. 8, pp. 1747-1756	
	10.	YAMAZAKI, H. et al., Cytochrome P450 sE1 and 2A6 enzymes as major catalysts for metabolic activation of nitrosodialkylamines and tobacco-related nitrosamines in human liver microsomes, Carcinogenesis (1992) Vol. 13, No. 10, pp. 1789-1794	
	11.	CAPLUS, DN 120:138085, Garnitskij et al., SU 1803032 A1, 1993/03/23, english abstract with notes from oral translation	
	12.	MAYS et al., Methoxsalen is potent inhibitor of caffeine in humans, Clin. Pharmacol. Ther., 42:621-626 (1987)	
	13.	MAENPAA et al., Biochem. Pharmacol., 48(7), (1994), 1363-9	
	14.	BENOWITZ, N. L. et al., Deficient c-oxidation of nicotine, Clinical Pharmacology and Therapeutics, 57(5): 590-594 (1995) (Abstract)	
	15.	Copy of International Search Report dated June 6, 1999	

Examiner
Signature

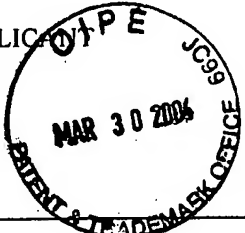
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FORM PTO-1449(Modified) (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 064658.0129		APPLICATION NO. 09/214,851	
LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT Edward M. SELLERS et al.			
				FILING DATE January 14, 1999		GROUP 1414	



U.S. PATENT DOCUMENTS													
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE							

FOREIGN PATENT DOCUMENTS													
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION							
						YES	NO						
1 cm	9 5 3 4 6 7 9	12/21/95	WIPO	—	—								

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)												
2 cm	Nakajima, M., et al., "Characterization of CYP2A6 involved in 3'-hydroxylation of cotinine in human liver microsomes", <i>J. Pharmacol. Exp. Therap.</i> , (1996) Vol. 277, No. 2, pp. 1010-1015.											
3	Nakajima, M., et al., "Role of human cytochrome P4502A6 in C-oxidation of nicotine", <i>Drug Metabol. Dispos.</i> , (1996) Vol. 24, No. 11, pp. 1212-1217.											
4	Tsujimoto, A., et al., "Potent inhibitory action of pilocarpine on hepatic drug metabolism", <i>Jpn. J. Pharmacol.</i> , (1972) Vol. 22, No. 5, 736.											
5	Tsujimoto, A., et al., "A study of the nature of pilocarpine inhibition of hepatic drug-metabolizing enzymes", <i>Biochem. Pharmacol.</i> , (1977) Vol. 26, No. 21, pp. 2072-2074.											
6	Foth, H., et al., "Nicotine Metabolism in isolated perfused lung and liver of phenobarbital- and benzoflavone-treated rats", <i>Arch. Toxicol.</i> , (1991) Vol. 65, No. 1, pp. 68-72.											
7	Kyerematen, G.A., et al., "Metabolism of nicotine by hepatocytes", <i>Biochem. Pharmacol.</i> , (1990) Vol. 40, No. 8, pp. 1747-1756.											
8	Yamazaki, H., et al., "Cytochrome P450 sE1 and 2A6 enzymes as major catalysts for metabolic activation of N-nitrosodialkylamines and tobacco-related nitrosamines in human liver microsomes", <i>Carcinogenesis</i> (1992) Vol. 13, No. 10, pp. 1789-1794.											

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Notice of References Cited

MAR 30 2004

Application/Control No.

09/214,851

Applicant(s)/Patent Under
Reexamination
SELLERS ET AL.

Examiner

Cybille Delacroix-Muirheid

Art Unit

1614

Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,653,987	08-1997	MODI et al.	424/400
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N	1803032 A1	03-1993	SU		
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	CAPLUS, DN 120:238085, Garnitskij et al., SU 1803032 A1, 1993/03/23, english abstract with notes from oral translation.
	V	MAYS et al., Methoxsalen is a Potent Inhibitor of Caffeine in Humans, Clin. Pharmacol. Ther., 42: 621-626 (1987).
	W	MAENPAA et al., Biochem. Pharmacol., 48(7), (1994), 1363-9.
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